

AMENDED IN SENATE MAY 26, 2006

AMENDED IN SENATE APRIL 26, 2006

AMENDED IN SENATE APRIL 6, 2006

SENATE BILL

No. 1260

Introduced by Senators Ortiz and Runner

February 9, 2006

An act to amend Sections 125118, 125119, 125119.3, and 125119.5 of, and to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1260, as amended, Ortiz. Reproductive health and research.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 7 2, 2004, general election (Proposition 71), establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in, the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute, including, but not limited to, establishing standards applicable to research funded by the institute.

Existing law prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the

amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses.

Existing law, which is not applicable to research funded under Proposition 71, and which would be repealed on January 1, 2007, requires the State Department of Health Services to, among other things, develop guidelines for research involving the derivation or use of embryonic stem cells, and to report annually to the Legislature.

This bill would delete the repeal date of those provisions, thus indefinitely extending their duration. *The bill would also revise the department's reporting duties, by requiring biennial rather than annual reports to the Legislature.*

Existing law applicable to fertility treatment requires that a physician and surgeon provide a patient with prescribed information and obtain the patient's informed consent prior to providing the fertility treatment.

This bill, with certain exceptions, would require a physician and surgeon, prior to conducting assisted oocyte production, as defined, or other method of ovarian retrieval for purposes of retrieving eggs for research or for developing medical therapies, to provide the subject with a standardized written summary of health and consumer issues and to obtain the subject's written and oral informed consent for the procedure.

Existing law prohibits a person from knowingly, for valuable consideration, purchasing or selling embryonic or cadaveric fetal tissue for research purposes.

This bill would prohibit human oocytes or embryos from being acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and would prohibit payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

The bill would declare that it is not to be construed to amend Proposition 71, and would encourage the ICOC to take prescribed actions, including, but not limited to, reviewing studies concerning the health risks and benefits of ovarian stimulation drugs, and undertaking further research.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The purpose of this act is to create protections for research
4 subjects and it should not be construed to affect any other form
5 of medical care.

6 (b) Scientific research can be most effectively achieved by
7 establishing protocols to protect, respect, and promote human
8 health, safety, dignity, autonomy, and rights in conducting
9 research.

10 (c) This act seeks to support the requirements already in
11 current law upholding the principle of voluntary and informed
12 consent and to tailor them to this new area of pioneering research
13 that utilizes human oocytes.

14 (d) The potential for exploitation of the reproductive
15 capabilities of women for commercial gain raises health and
16 ethical concerns that justify the prohibition of payment for
17 human oocytes.

18 SEC. 2. Section 125118 of the Health and Safety Code is
19 amended to read:

20 125118. (a) The department shall develop guidelines for
21 research involving the derivation or use of human embryonic
22 stem cells in California.

23 (b) In developing the guidelines specified in subdivision (a),
24 the department may consider other applicable guidelines
25 developed or in use in the United States and in other countries,
26 including, but not limited to, the Guidelines for Research Using
27 Human Pluripotent Stem Cells developed by the National
28 Institutes of Health and published in August 2000, and corrected
29 in November 2000, and the Guidelines for Human Embryonic
30 Stem Cell Research issued by the National Research Council and
31 Institute of Medicine of the National Academies in 2005.

32 SEC. 3. Section 125119 of the Health and Safety Code is
33 amended to read:

34 125119. (a) (1) All research projects involving the
35 derivation or use of human embryonic stem cells shall be
36 reviewed and approved by an institutional review board that is
37 established in accordance with federal regulations, including Part
38 46 (commencing with Section 46.101) of Subchapter A of

1 Subtitle A of Title 45 of the Code of Federal Regulations, prior to
2 being undertaken. Any such institutional review board shall, in
3 its review of human embryonic stem cell research projects,
4 consider and apply the guidelines developed by the department
5 pursuant to Section 125118. An institutional review board may
6 require modifications to the plan or design of a proposed human
7 embryonic stem cell research project as a condition of approving
8 the research project.

9 (2) For purposes of this article, “IRB” means an institutional
10 review board described in paragraph (1).

11 (b) Not less than once per year, an IRB shall conduct
12 continuing review of human embryonic stem cell research
13 projects reviewed and approved under this section in order to
14 ensure that the research continues to meet the standards for IRB
15 approval. Pursuant to its review in accordance with this
16 subdivision, an IRB may revoke its prior approval of research
17 under this section and require modifications to the plan or design
18 of a continuing research project before permitting the research to
19 continue.

20 SEC. 4. Section 125119.3 of the Health and Safety Code is
21 amended to read:

22 125119.3. (a) Each IRB that has reviewed human embryonic
23 stem cell research pursuant to Section 125119 shall report to the
24 department, annually, on the number of human embryonic stem
25 cell research projects that the IRB has reviewed, and the status
26 and disposition of each of those projects.

27 (b) Each IRB shall also report to the department regarding
28 unanticipated problems, unforeseen issues, or serious continuing
29 investigator noncompliance with the requirements or
30 determinations of the IRB with respect to the review of human
31 embryonic stem cell research projects, and the actions taken by
32 the IRB to respond to these situations.

33 SEC. 5. Section 125119.5 of the Health and Safety Code is
34 amended to read:

35 125119.5. (a) The department shall at least annually review
36 reports from IRBs pursuant to Section 125120, and may revise
37 the guidelines developed pursuant to Section 125118, as it deems
38 necessary.

39 (b) The department shall report ~~annually~~ *biennially* to the
40 Legislature on human embryonic stem cell research activity.

1 These ~~annual~~ *biennial* reports shall be compiled from the reports
2 from IRBs pursuant to Section 125120.

3 SEC. 6. Chapter 2 (commencing with Section 125330) is
4 added to Part 5.5 of Division 106 of the Health and Safety Code,
5 to read:

6
7 CHAPTER 2. PROCURING OF OOCYTES FOR RESEARCH
8

9 125330. The following definitions shall apply to this chapter:

10 (a) “Assisted oocyte production” or “AOP” means surgical
11 extraction of oocytes following pharmaceutically induced
12 manipulation of oocyte production through the use of ovarian
13 stimulation.

14 (b) “Oocyte” means a female egg or egg cell of a human
15 female.

16 (c) “Subject” means any person undergoing AOP or any
17 alternative method of ovarian retrieval for research or for the
18 development of medical therapies, including those who would
19 not meet the definition of “subject” under 45 C.F.R. 46.102.

20 (d) “Alternate method of oocyte retrieval” means a method of
21 oocyte retrieval that does not involve the pharmaceutically
22 induced manipulation of oocyte production.

23 125335. (a) Prior to conducting AOP or any alternative
24 method of ovarian retrieval on a subject for the purpose of
25 procuring oocytes for research or the development of medical
26 therapies, a physician and surgeon shall provide to the subject a
27 standardized medically accurate written summary of health and
28 consumer issues associated with AOP and any alternative
29 methods of oocyte retrieval. The failure to provide to a subject
30 this standardized medically accurate written summary constitutes
31 unprofessional conduct within the meaning of Chapter 5
32 (commencing with Section 2000) of Division 2 of the Business
33 and Professions Code.

34 (b) The summary shall include, but not be limited to,
35 medically accurate disclosures concerning the potential risks of
36 AOP or any alternative method of oocyte retrieval, including the
37 risks associated with the surgical procedure and with using the
38 drugs, medications, and hormones prescribed for ovarian
39 stimulation during the AOP process or any alternative method of
40 oocyte retrieval.

(c) For purposes of subdivision (a), “written summary of health and consumer issues” means the guide published and updated by the American Society for Reproductive Medicine entitled, “Assisted Reproductive Technology: A Guide for Patients” or an alternative written medically accurate document prepared by a recognized authority on oocyte retrieval for medical research that also meets the criteria included in this section. This alternative document may be one that has been approved and recommended by the State Department of Health Services pursuant to Section 125118 and shall include all of the following:

(1) The document shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications. The document shall be written in layperson’s language and shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the document shall be conveyed to the subject orally in easy to understand and nontechnical terms.

(2) The document shall include additional resources for, or list additional sources of, medical information on health and safety issues surrounding oocyte retrieval.

125340. (a) Prior to providing AOP or any alternative method of ovarian retrieval to a subject for the purposes of medical research or development of medical therapies, a physician and surgeon shall obtain written and oral informed consent for the procedure from the subject. Informed consent for the purposes of this chapter shall comply with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

(b) The failure to obtain written informed consent from the subject constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code. Nothing in this section shall be construed to relieve the physician and surgeon from other existing duties under the law, including, but not limited to, the duty to obtain a subject’s informed consent after fully explaining the proposed procedure. The requirement that a physician and surgeon provide the standardized written summary pursuant to

1 Section 125335 is in addition to, and does not supplant, other
2 existing legal requirements regarding informed consent,
3 including, but not limited to, compliance with the Protection of
4 Human Subjects in Medical Experimentation Act (Chapter 1.3
5 (commencing with Section 24170) of Division 20.

6 (c) This section shall not affect the suitability or availability of
7 oocytes procured for research before January 1, 2006, if the
8 oocytes were donated pursuant to protocols or standards that are
9 generally recognized and accepted by national or international
10 scientific bodies.

11 (d) Any written document required pursuant to this section
12 shall adhere to simplified reading standards, including, but not
13 limited to, those generally accepted and required for government
14 publications, and in layperson's language. The document shall be
15 made available in languages spoken by subjects in the study if
16 their proficiency is largely in a language other than English. All
17 information in the written informed consent document shall also
18 be conveyed to the subject orally in easy to understand and
19 nontechnical terms.

20 125341. An institutional review board (IRB) that reviews and
21 approves medical and scientific research shall require all of the
22 following of any research program or project that comes under its
23 review that involves AOP or any alternative method of oocyte
24 retrieval:

25 (a) That it include a written summary as required under
26 Section 125335 that would include information on health risks
27 and potential adverse consequences of the procedure and
28 describe the manner in which the subject will receive and review
29 this written summary.

30 (b) That it obtain informed consent in compliance with the
31 Protection of Human Subjects in Medical Experimentation Act
32 (Chapter 1.3 (commencing with Section 24170) of Division 20).

33 (c) That it provide the subject with an objective and accurate
34 statement about the existing state of the research for which the
35 subject is providing oocytes.

36 (d) That it perform psychological and physical screening for
37 all subjects prior to the oocyte retrieval procedure, following
38 generally recognized standards for the subject's health and
39 safety.

1 (e) That it ensure that after conducting AOP or any alternative
2 method of oocyte retrieval on a subject, the subject be given a
3 postprocedure medical examination at a time within the standard
4 of care to determine if the subject has experienced an adverse
5 health effect that is a result of the procedure. The subject shall be
6 informed that she has the right to a second opinion if she has any
7 medical concerns.

8 (f) That it ensure that the subject has access to and coverage
9 for medical care for any adverse consequence that is a direct
10 result of the procedure. The research program or project shall
11 ensure that payment or coverage of resulting medical expenses be
12 provided by the program or project and that a summary of the
13 arrangements the procuring entity has made for coverage or
14 payment for medical care related to AOP or any alternative
15 method of oocyte retrieval is provided to the subject prior to the
16 procedure.

17 (g) That it provide a summary informing the subject that
18 oocytes may not be sold or transferred for valuable consideration
19 except as set forth in Section 125350.

20 (h) That it provide disclosure if the physician and surgeon and
21 his or her immediate family members have any professional
22 interest in the outcome of the research or of the oocyte retrieval
23 procedure and, if so, that it provide disclosure that he or she
24 carries the interest of both the subject and the success of the
25 research.

26 (i) That it establish and maintain a written record to include,
27 but not be limited to, all of the following components, which
28 information shall be made publicly available, on at least a
29 biennial basis:

30 (1) The demographics of subjects, including, but not limited
31 to, their age, race, primary language, ethnicity, income bracket,
32 and ZIP Code of current residence.

33 (2) Information for every oocyte, sperm, gamete, somatic cell,
34 embryo donation, or product of somatic cell nuclear transfer that
35 has been donated, created, or used. This record should be
36 sufficient to determine the provenance and disposition of those
37 materials.

38 (3) A record of all adverse health outcomes, including, but not
39 limited to, incidences and degrees of severity, resulting from the
40 AOP or any alternative method of oocyte retrieval.

1 (j) The information included in the written record pursuant to
2 subdivision (i) shall not disclose individual information about
3 subjects, and shall be confidential and is deemed protected by
4 subject privacy provisions of law.

5 125343. Any employee or relative of an employee of a
6 research organization or body is prohibited from being a subject
7 in the research.

8 125344. The physician and surgeon performing the AOP or
9 any alternative method of oocyte retrieval shall not have a
10 financial interest in the outcome of the research.

11 125345. Pursuant to guidelines adopted by the Research
12 Council and Institute of Medicine of the National Academies,
13 researchers shall offer subjects an opportunity to document their
14 preferences regarding future uses of their donated materials. The
15 consent process shall fully explore whether donors have
16 objections to any specific forms of research to ensure that their
17 wishes are honored.

18 125346. Any procedures for procuring oocytes in this state
19 for research or the development of medical therapies shall meet
20 all of the standards for subjects included in this chapter. All eggs
21 procured outside of this state for research taking place in this
22 state shall meet these same standards. All egg extractions for
23 research shall be approved by an institutional review board
24 pursuant to Section 125341.

25 125350. No human oocyte or embryo shall be acquired, sold,
26 offered for sale, received, or otherwise transferred for valuable
27 consideration for the purposes of medical research or
28 development of medical therapies. For purposes of this section,
29 “valuable consideration” does not include reasonable payment
30 for the removal, processing, disposal, preservation, quality
31 control, and storage of oocytes or embryos.

32 125355. No payment in excess of the amount of
33 reimbursement of direct, out-of-pocket expenses shall be made to
34 any research subject to encourage her to produce human oocytes
35 for the purposes of medical research. There shall be no
36 reimbursement for lost wages.

37 SEC. 7. (a) This act shall not be construed to amend
38 Proposition 71, approved by the voters at the November 2, 2004,
39 general election.

1 (b) The Independent Citizen's Oversight Committee (ICOC)
2 established pursuant to Section 125290.15 of the Health and
3 Safety Code is encouraged to review existing studies concerning
4 the health risks and benefits of ovarian stimulation drugs used for
5 assisted oocyte production, identify gaps in existing knowledge
6 concerning health risks and benefits, and undertake further
7 research as the ICOC deems necessary to characterize the risks
8 and benefits of those drugs.

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